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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
|---|-------------|----------------------|---------------------|---------------------|
| 08/692,084 | 08/08/1996 | MOSES RODRIGUEZ | 1199-1-001-C | 3108 |
| 7590 | 03/11/2005 | | EXAMINER | |
| DAVID A JACKSON KLAUBER AND JACKSON 411 HACKENSACK AVENUE HACKENSACK, NJ 07601 | | | | DUFFY, PATRICIA ANN |
| | | ART UNIT | PAPER NUMBER | 1645 |

DATE MAILED: 03/11/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

| | | |
|------------------------------|------------------------|---------------------|
| Office Action Summary | Application No. | Applicant(s) |
| | 08/692,084 | RODRIGUEZ ET AL. |
| | Examiner | Art Unit |
| | Patricia A. Duffy | 1645 |

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) Responsive to communication(s) filed on 20 December 2004.
- 2a) This action is FINAL. 2b) This action is non-final.
- 3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) Claim(s) 1-4,9-14 and 19-22 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) Claim(s) 20-22 is/are allowed.
- 6) Claim(s) 1-4,9-14 and 19 is/are rejected.
- 7) Claim(s) _____ is/are objected to.
- 8) Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) The specification is objected to by the Examiner.
- 10) The drawing(s) filed on _____ is/are: a) accepted or b) objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
 - a) All b) Some * c) None of:
 1. Certified copies of the priority documents have been received.
 2. Certified copies of the priority documents have been received in Application No. _____.
 3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

| | |
|---|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____. |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____. | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| | 6) <input type="checkbox"/> Other: _____. |

RESPONSE TO AMENDMENT

The amendment filed 12-20-04 and response filed 11-22-04 have been entered into the record. Claims 1-4, 9-14 and 19 are pending and under examination. Claims 20-22 are allowable.

The text of Title 35 of the U.S. Code not reiterated herein can be found in the previous office action.

Rejections Maintained

Claim 19 is rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claim 1 of U.S. Patent No. 5,591,629. Although the conflicting claims are not identical, they are not patentably distinct from each other because the monoclonal antibody of the issued patent anticipates the claims recited herein.

Applicant's arguments have been carefully considered but are not persuasive for the reasons made of record and the rebuttal herein. Applicants again point out that a synthetic autoantibody is an autoantibody made by a synthetic process. In contrast to Applicants assertion, the specification does not specifically define the metes and bounds of "synthetic autoantibody" as limited to the process asserted by Applicant. Again this is not persuasive, it is well established that the process of making does not convey a patentable distinction on the product. The purification or production of a product by a particular process (i.e. the instant synthetic) does not impart novelty or unobviousness to a product when the product is taught by the prior art. This is particularly true, when the properties of the product are not changed by the process in an unexpected manner. *In re Thorpe*, 227 USPQ 964 (CAFC 1985); *In re Marosi*, 218 USPQ 289, 292-293 (CAFC 1983); and *In re Brown*, 173 USPQ 685 (CCPA 1972). Therefore, even if a particular process used to prepare a product is novel and unobvious over the prior art, the product *per se*,

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even when limited to the particular process, is unpatentable over the same product taught by the prior art. *In re King*, 107 F.2d 618, 620, 43 USPQ 400, 402 (CCPA 1939); *In re Merz*, 97 F.2d 559, 601, 38 USPQ 143-45 (CCPA 1938); and *United States v. Ciba-Geigy Corp.*, 508 F.supp. 1157, 1171, 211 USPQ 529, 543 (DNJ 1979). Therefore, the process of making asserted by Applicants does not structurally define over the monoclonal antibody patent. Further, the examiner maintains that the monoclonal antibody of the patent is in fact an autoantibody, because it binds self-antigen. It is noted that making the monoclonal antibody is in fact a "synthetic process" requiring the hand of man. The particular species of the patent therefore anticipates the genus.

The rejection is maintained.

Claims 1-4, 9-14 and 19 stand rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for methods for stimulating remyelination or treating a demyelinating disease in a mammal by administering to a mammal an effective amount of monoclonal antibodies that induce remyelination of the central nervous system, the specific monoclonal antibody SCH79.05 and synthetic monoclonal autoantibodies, it does not reasonably provide enablement for the specific monoclonal autoantibodies A2B5, O1, O4, HNK-1 and synthetic autoantibodies for reasons made of record in all the previous office actions of record and reasons of record herein.

Applicant's arguments have been carefully considered but are not persuasive. Applicants argue that the antibodies can be obtained and/or are for commercial sale to the public. This again is not persuasive. Applicant's specification references, and claims specifically identified monoclonal antibodies by specific name. For example, at page 9, lines 30-33, the specification recites ".. using SCH 94.03, SCH 79.08, O1, O4, A2B5, and HNK-1 monoclonal antibodies...". The specification does not reference the antibodies by "a monoclonal antibody that binds the HNK-1 antigen". The antibodies are listed by specific clone name. This interpretation is consistent with the listing of Applicant's two

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monoclonal antibody clones. In each and every use of the recited and claimed monoclonal antibodies, the concept of any antibody to bind the antigen as defined by the prior art monoclonal antibody of that specific identification is not conveyed by the specification at the time of filing. One of skill in the art reading the passages of the specification would look to the monoclonal antibody of that specific name and not "others that bind the same antigen" as argued by Applicant. Thus, these antibodies must be deposited for patent purposes. Where the invention involves a biological material and words alone cannot sufficiently describe how to make and use the invention in a reproducible manner, access to the biological material may be necessary for the satisfaction of the statutory requirements for patentability under 35 U.S.C. 112. Courts have recognized the necessity and desirability of permitting an applicant for a patent to supplement the written disclosure in an application with a deposit of biological material that is essential to meet some requirement of the statute with respect to the claimed invention. See, e.g., *Ajinomoto Co. v. Archer-Daniels-Midland Co.*, 228 F.3d 1338, 1345-46, 56 USPQ2d 1332, 1337-38 (Fed. Cir. 2000), cert. denied, 121 S.Ct. 1957 (2001)(explaining how deposit may help satisfy enablement requirement); *Merck and Co., Inc. v. Chase Chemical Co.*, 273 F. Supp. 68, 155 USPQ 139 (D. N.J. 1967); *In re Argoudelis*, 434 F.2d 666, 168 USPQ 99 (CCPA 1970). The record establishes that the commercial sale of the claimed monoclonal antibodies is (a) restricted and (b) specifically indicates "not for therapeutic use". As such, the citation of the specific monoclonal antibodies as commercially available does not meet the requirements for enablement. The need for a biological deposit in a patent is obviated if it is readily available to the public. The record establishes that it is not "readily available" because it has restrictions and further indicates "not for therapeutic use" on the data sheets of record. Applicants admit that the materials of the prior art submitted to obviate the rejection of record are restricted in use and practice. Applicant's arguments drawn to other antibodies are not persuasive. The issue is that the particularly claimed monoclonal antibodies do not have unrestricted public availability and

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use. They are restricted and as such do not meet the requirements for patent deposit. Applicants argue that it is not the examiner to determine whether an Applicant has the freedom to operate or whether a license is necessary for use. This is not persuasive, the issues remains an enablement issue. In the absence of a public deposit of the hybridoma producing the antibodies, one skilled in the art cannot practice the invention. This is an enablement issue and not a licensing issue. The claimed antibodies have "restricted availability" and "restricted use" and as such, cannot and do not meet the requirement for deposit and enablement under 35 USC 112, first paragraph of how to make and use *the claimed invention*.

The rejection is maintained.

Claim 19 stands rejected under 35 U.S.C. 102(b) as being clearly anticipated by Abo et al (J. Immunol. 127:1024-1029, 1981) or American Type Culture Collection, 1992, page 435 is maintained for reasons made of record and reasons made of record herein.

Applicant's arguments have been carefully considered but are again not persuasive. Applicant disagrees with the examiner position that a new use for an old composition does not render the old composition again patentable. This is not persuasive, it is well settled case law that an old composition does not become patentable based upon a new use. The discovery of a previously unappreciated property of a prior art composition, or of a scientific explanation for the prior art's functioning, does not render the old composition patentably new to the discoverer." *Atlas Powder Co. v. Ireco Inc.*, 190 F.3d 1342, 1347, 51 USPQ2d 1943, 1947 (Fed. Cir. 1999). Thus the claiming of a new use, new function or unknown property which is inherently present in the prior art does not necessarily make the claim patentable. *In re Best*, 562 F.2d 1252, 1254, 195 USPQ 430, 433 (CCPA 1977). Applicant also submits that the HNK-1 antibody hybridoma does not anticipate claim 19, which is directed against a synthetic autoantibody composition. This is not persuasive, the hybridoma contains the HNK-1 monoclonal antibody. The composition comprises the

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antibody. Applicant further argues that the monoclonal antibody is not a synthetic autoantibody. This is not persuasive, "synthetic autoantibody" is not particularly defined in the specification. The examiner maintains that the monoclonal antibody of the patent is in fact an autoantibody, because it binds self-antigen. It is noted that making the monoclonal antibody is in fact a "synthetic process" requiring the hand of man. The purification or production of a product by a particular process (i.e. the instant recombinant) does not impart novelty or unobviousness to a product when the product is taught by the prior art. This is particularly true, when the properties of the product are not changed by the process in an unexpected manner. *In re Thorpe*, 227 USPQ 964 (CAFC 1985); *In re Marosi*, 218 USPQ 289, 292-293 (CAFC 1983); and *In re Brown*, 173 USPQ 685 (CCPA 1972). Therefore, even if a particular process used to prepare a product is novel and unobvious over the prior art, the product *per se*, even when limited to the particular process, is unpatentable over the same product taught by the prior art. *In re King*, 107 F.2d 618, 620, 43 USPQ 400, 402 (CCPA 1939); *In re Merz*, 97 F.2d 559, 601, 38 USPQ 143-45 (CCPA 1938); and *United States v. Ciba-Geigy Corp.*, 508 F.supp. 1157, 1171, 211 USPQ 529, 543 (DNJ 1979). Therefore the recitation of "synthetic" does not convey any particular structural or functional difference as compared to the antibody cited as prior art.

Status of Claims

Claims 20-22 are allowed claims 1-4, 9-14 and 19 are rejected.

Conclusion

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within

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TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Patricia A. Duffy whose telephone number is 571-272-0855. The examiner can generally be reached on M-Th 6:30 am - 6:00 pm. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Lynette Smith can be reached on 571-272-0864.

The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Patricia A. Duffy
Patricia A. Duffy

Primary Examiner

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